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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,271	03/12/2004	Robert J. Garabedian	04-056 US01	7198

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,271	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,18-29,31-54,56,57,65-74,76-90,92,93,101-112,114,115 and 123-125* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims objected to are 8,11-17,20-23,30,33-36,55,58,66-68,75,77,78,91,94-100,103-106,113,116-122,124 and 125.

DETAILED ACTION

Claim Objections

1. Claims 20-23, 33-36, 66-68, 77, 78, 103-106, 124, and 125 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The objected to claims recite a method, and base their dependency on claims for a device, and therefore fail to further limit the device claims because they fail to present any structural elements.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7, 9, 10, 24-29, 31, 32, 48-54, 56, 57, 69-74, 76, 85-90, 92, 93, 102, 107-112, 114, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al. (US Patent no. 6,587,733 – hereinafter Cross).

4. In regard to claims 1, 24, 48, 69, 85, and 107, Cross discloses a pair of percutaneous lead bodies 12, 14, col 3 lines 26-28. Lead body 12 is considered to be the "first stimulation lead", and lead body 14 is considered to be the "secondary." Figure 2 shows the two lead bodies 12, 14 in parallel configuration with one another; it is stated

that this particular configuration of two leads, coupled parallel to each other, provides the advantages of a surgical pad without the invasive methods of implantation, col 3 lines 20-25. Figure 1 depicts the lead bodies as being elongated. At least one stimulation element 16 is mounted on the leads, 12, and 14. The lead bodies 12, 14 are bonded together by a urethane bridge 20, which are spaced along the lead bodies 12, 14, col 3 lines 55-58, and serve as the coupling mechanisms. The leads 12 and 14 are coupled together, but do not slidably engage one another. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to separate the leads and allow for a movable coupling mechanism since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art[1] and it has also been held that making a part of a device movable without producing any new and unexpected result involves only routine skill in the art[2]. [1]*Nerwin v. Erlichman*, 168 USPQ 177, 179; [2]*In re Lindberg*, 93 USPQ 23 (CCPA 1952).

5. Further in regards to claims 24 and 69, wherein applicant claims "two secondary stimulation leads", the Examiner hold that this would have been obvious to one of ordinary skill in the art at the time the invention was made since it involves a mere duplication of essential working parts of a device, and requires only routine skill in the art. *St. Regis Paper Co. V. Bemis Co.*, 193 USPQ 8.

6. In regard to claims 2, 25, 49, 70, 86, and 108 Figure 5 of Cross discloses that the lead bodies 12 and 14 are cylindrical, col 3 lines 31-33. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a

lead with a cylindrical body since Cross explicitly shows a substantially cylindrical lead body, and teaches that it was well known in the medical lead art at that time.

7. In regard to claims 3, 50, 87, and 109, Cross describes the invention substantially as claimed, except does not describe the cross-sectional dimension as being 5 mm or less. However, Cross does teach that the medical lead 10, comprised of lead bodies 12 and 14 has sufficiently small cross-section so as to permit percutaneous implantation in the targeted region for stimulation, col 3 lines 17-19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to design an implantable medical lead with an appropriate cross-sectional dimension since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 198C).

8. In regard to claims 4, 5, 26, 27, 51, 52, 71, 72, 89, 110 and 111 spaced along lead bodies 12 and 14 is at least one electrode 16, col 3 lines 34-35.

9. In regard to claims 6, 28, 53, and 73, another embodiment of Cross is to have a lead body having one-directional, focused stimulation, col 2 lines 13-15. This is done by coating parts of the electrode with a non-conductive polymer to effectively allow stimulation in one direction, col 4 lines 42-59.

10. In regard to claims 7, 29, 54, 74, 90, and 112, Cross states that "at least one" electrode 16 is space along lead bodies 12 and 14. Figures 1 and 3 each depict electrode areas 16 in excess of one. This would have been obvious to one of ordinary skill in the art at the time the invention was made since it involves mere duplication of essential working elements.

11. In regard to claims 9, 31, 56, 76, 92, and 114 the coupling bridge 20 that couples lead 12 to lead 14 is shown on the distal end of the lead bodies 12, 14.

12. In regard to claims 10, 57, 93 and 115, Figure 3 of Cross depicts lead 14 is shorter than lead 12. From this depiction, it would have been obvious to one of ordinary skill in the art.

13. In regard to claims 19, 32, and 102, Cross teaches that an implantable neurological pulse generator or other stimulation device, col 3 lines 46-48, produce stimulation pulses delivered from the leads.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 18, 20-23, 33-44, 46, 47, 65-68, 77-84, 101, 103-106, and 123-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al. (US Patent no. 6,587,733 – hereinafter Cross) in view of Morgan et al. (US Patent no. 6,988,007).

16. In regard to claims 20, 21, 33, 34, 37, 38, 66, 67, 77-80, 103, 104, 124, and 125, Cross describes a system wherein two lead bodies 12 and 14 are percutaneously inserted into the spinal cord. Cross also teaches that it is well known in the art that stimulation of the spinal cord is often accomplished by implanting medical leads into the epidural space of the spinal cavity, col 1 lines 20-23. However, Cross does not describe

the leads as being as being delivered by sliding a secondary lead along the first lead. Morgan et al. discloses a medical lead intended for insertion into the cardiac anatomy, however, the structure can be applied to function in the method claimed. The lead described by Morgan et al. has two lead bodies 22 and 24. Lead body 22 is described as the inner lead body, and is configured to be slidable along the outer lead body 24. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made configure the leads for sliding along one another in order to facilitate placement of two leads into the same location for stimulation. Further it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art[1] and it has also been held that making a part of a device movable without producing any new and unexpected result involves only routine skill in the art[2]. [1]*Nerwin v. Erlichman*, 168 USPQ 177, 179; [2]*In re Lindberg*, 93 USPQ 23 (CCPA 1952).

17. Further in regard to claims 33 and 77, wherein applicant claims "two secondary stimulation leads", the Examiner hold that this would have been obvious to one of ordinary skill in the art at the time the invention was made since it involves a mere duplication of essential working parts of a device, and requires only routine skill in the art. *St. Regis Paper Co. V. Bemis Co.*, 193 USPQ 8.

18. In regard to claims 22, 35, 39, 42, 43, 44, 81, and 105, the objective of Cross is to provide electrical stimulation to the spinal cord, and it would be obvious that the electrical energy would be applied from the electrode elements 16, since it is well known.

19. In regard to claims 23, 36, 41, 68, and 106, Cross provides stimulation of the spinal cord, and it is well known in the art that stimulation along the spinal column is an effective method of treating chronic pain.

20. In regard to claim 40, Cross teaches that stimulation pulses delivered from the leads are produced by an implantable neurological pulse generator or other stimulation device, col 3 lines 46-48.

21. In regard to claims 18, 45, 65, 82, 101, and 123, Cross in view of Morgan et al. substantially describe the invention as claimed except for the use of a third stimulation lead. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a third lead to the structure since it involves a mere duplication of essential working parts of a device, and requires only routine skill in the art. *St. Regis Paper Co. V. Bemis Co.*, 193 USPQ 8.

22. In regard to claims 46, 47, 83, and 84, Cross states that the two lead bodies 12 and 14 are delivered to the desired stimulation site via a modified Touhy needle.

Allowable Subject Matter

23. Claims 8, 11-17, 30, 55, 58-64, 75, 91, 94-100, 113, and 116-122 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Erickson (US 2005/0004639) describes an implantable lead having a first lead body and second lead body having a connected member coupled in between. Stypulkowski (US Patent no. 6,909,918) shows a device for implanting two lead bodies for neurological stimulation. Feler et al. (US Patent no. 6,002,964) describes methods for epidural nerve root stimulation.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BTG